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PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:	Confirmation No.: 8916
Steven Sichuan He *et al.*	Art Unit: 1638
Appln. No.: 10/024,632	Examiner: Stuart F. Baum
Filed: December 19, 2001	Atty. Docket: 16517.327 / 38-21(51837)B

Title: **Nucleic Acid Molecules Associated With Plant Cell Proliferation and Growth and Uses Thereof**

APPELLANT'S BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
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Sir:

This is an Appeal from the Final Rejection of claims 3-5 in the above-captioned patent application. A Notice of Appeal was filed on February 22, 2005. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter.

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

Appellant identifies the following judicial proceeding, which may have a bearing the Board's decision in the present Appeal. On May 27, 2004, the Real Party in Interest in the above-captioned matter filed an appeal to the United States Court of Appeals for the Federal Circuit ("Federal Circuit") from a decision by the Board in *In re Fisher.* (U.S. Appln No.

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09/619,643, B.P.A.I. Appeal No. 2002-2046, Fed. Cir. Case No. 04-1465). The Federal Circuit's decision in *In re Fisher* may have a bearing on the Board's decision with regard to at least one of the grounds of rejection in the present appeal. A copy of the Board's decision in Appeal No. 2002-2046 is attached hereto as Appendix B.

In addition, Appellant also identifies the following additional Board decisions which may have a bearing on the instant appeal: U.S. Appln. No. 09/654,617, B.P.A.I. Appeal No. 2003-1744; U.S. Appln. No. 09/620,392, B.P.A.I. Appeal No. 2003-1746; U.S. Appln. No. 09/540,232, B.P.A.I. Appeal No. 2003-1137; U.S. Appln. No. 09/440,687, B.P.A.I. Appeal No. 2003-1504; U.S. Appln. No. 09/565,240, B.P.A.I. Appeal No. 2003-1135; U.S. Appln. No. 09/540,215, B.P.A.I. Appeal No. 2003-0996; U.S. Appln. No. 09/552,087, B.P.A.I. Appeal No. 2004-1772; and U.S. Appln. No. 09/206,040, B.P.A.I. Appeal No. 2002-0078. Copies of the Board's decisions in these Appeals are also attached hereto in Appendix B.

Appellant also identifies the following pending appeals before the Board which may have a bearing on the instant appeal: U.S. Appln. No. 09/233,218, B.P.A.I. Appeal No. 2004-1725; U.S. Appln. No. 09/540,234, B.P.A.I. Appeal No. 2003-1073; U.S. Appln. No. 09/333,535, B.P.A.I. Appeal No. 2003-1939; U.S. Appln. No. 09/666,355, B.P.A.I. Appeal No. 2004-1034; U.S. Appln. No. 09/552,086, B.P.A.I. Appeal No. 2003-1074; U.S. Appln. No. 09/637,086, B.P.A.I. Appeal No. 2004-1273; U.S. Appln. No. 09/540,235, B.P.A.I. Appeal No. 2004-1275; U.S. Appln. No. 09/553,094, B.P.A.I. Appeal No. 2004-1406; U.S. Appln. No. 09/267,199, B.P.A.I. Appeal No. 2004-2136; U.S. Appln. No. 09/521,640, B.P.A.I. Appeal No. 2004-1666; U.S. Appln. No. 09/371,146, B.P.A.I. Appeal No. 2004-

1272; U.S. Appln. No. 09/421,106, B.P.A.I. Appeal No. 2004-1773; and U.S. Appln. No. 09/732,627, B.P.A.I. Appeal No. 2004-1480.[1]

3. Status of Claims

Claims 3-5 are pending. Claim 6 is allowed. Claims 1-2 and 7-34 were cancelled without prejudice to or disclaimer of the subject matter claimed therein in a response to office action filed August 19, 2004. Claims 3-5 stand finally rejected under 35 U.S.C. § 112, first paragraph. Appellant appeals the rejections of claims 3-5.

4. Summary of Claimed Subject Matter

The claimed subject matter is directed to an isolated nucleic acid molecule comprising a nucleotide sequence, or its complement, which can encode a polypeptide having an amino acid sequence that is substantially identical to a sequence of SEQ ID NO: 2. Specification at page 4, lines 14-16 and lines 20-21, and page 15, lines 10-24. The claimed subject matter is also directed to an isolated nucleic acid molecule comprising a nucleic sequence, or its complement, which can hybridize under stringent conditions to a second nucleic acid sequence which can encode a protein with substantial identity to SEQ ID NO: 2. Specification at page 4, lines 16-18 and lines 20-21, and page 17, lines 9-12. The claimed subject matter is also directed to an isolated nucleic acid sequence which encodes an amino acid sequence comprising SEQ ID NO: 2 containing conservative amino acid substitutions. Specification at page 15, line 19 through page 16, line 12. A copy of the claims on appeal is attached hereto as Appendix A.

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[1] Appellant notes that these appeals have been, or have requested that these appeals be suspended pending a final determination in *In re Fisher*.

5. Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection to be reviewed in this Appeal are:

(a) pending claims 3-5 stand rejected under 35 U.S.C. § 112, first paragraph for alleged insufficient written description; and

(b) pending claims 3-5 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement.

6. Argument

A. Summary of Appellant's Position

Appellant has provided an adequate description of the claimed nucleic acid molecules that demonstrates Appellant's possession of the claimed invention. The claimed nucleic acid molecules, for example, the nucleic acid molecules comprising the nucleic acid sequence that can encode a polypeptide having an amino acid sequence that is substantially identical to the sequence of SEQ ID NO: 2, have been described by the recitation of common structural features, *e.g.* nucleotide sequences encoding the amino acid sequence of SEQ ID NO: 2, which distinguishes molecules in the claimed genus from molecules not in the claimed genus. Because the specification demonstrates that Appellant had possession of (and have provided an adequate description of) the claimed genera of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

Appellant has also provided sufficient disclosure in the specification to enable a person skilled in the art to make and/or use the invention. The specification clearly enables at least the methods of making and using the invention as set forth in the Examples. Furthermore, an analysis of the criteria presented by *In re Wands*, 858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1998), indicates that no undue experimentation would be required to make and use

the claimed invention. Thus, the specification satisfies the enablement requirement of 35 U.S.C. § 112.

B. The Specification Provides An Adequate Written Description of the Claimed Invention

The adequacy of the written description of claims 3-5 has been challenged by the Examiner because the claimed subject matter was allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention," "for the reasons of record set forth in the Official action mailed 5/19/2004." Final Action mailed November 19, 2004 ("Final Action") at pages 2-3.

The Examiner acknowledges that Appellant has "disclosed a nucleic acid sequence SEQ ID NO:1, encoding SEQ ID NO:2." Final Action, at page 3. However, the Examiner argues that Appellant has allegedly not described the claimed nucleic acid molecules. The basis of the rejection is that Appellant has not "disclosed any nucleic acid sequence encoding a polypeptide having at least 60% sequence identity with SEQ ID NO:2, or a nucleic acid sequence which can hybridize under stringent conditions to a nucleic acid sequence encoding a polypeptide having 60% sequence identity to SEQ ID NO:2, or a nucleic acid sequence encoding an amino acid sequence comprising SEQ ID NO:2 containing conservative amino acid substitutions." Final Action, at page 4. The Examiner further alleges that Appellant has not disclosed "essential regions of SEQ ID NO:2 that are required for the proper activity of the protein" and "a representative number of sequences encoding a protein with the same activity as SEQ ID NO:2 wherein one skilled in the art would be able to determine the essential domains that are required for the proper activity of

the protein." *Id.* The examiner's objections thus boil down to two alleged failures in the specification: failure to "describe a representative number of polynucleotide sequences encoding SEQ ID NO:2 falling within the scope of the claimed genus of polynucleotides" and failure to "identify essential regions of SEQ ID NO:2." Office Action mailed May 19, 2004, at pages 4-5. Contrary to the Examiner's allegation, the specification provides an adequate description of the claimed invention because it demonstrates to one skilled in the art that Appellant was in possession of the claimed genera of nucleic acid molecules when the application was filed.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Appellant needs not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification. *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981)). Thus, in order for Appellant to describe each and every molecule encompassed by the claims, it is not required that every

aspect of those nucleic acid molecules (*e.g.*, "essential regions") be disclosed. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584 (if a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met)

It is well-settled law that each nucleic acid molecule within a claimed genus does not need to be described by its complete structure. An adequate written description of a genus of nucleic acids, such as those recited in claims 3-5, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997) (emphasis added). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.* In contrast to the mere name "cDNA" provided in *Eli Lilly*, Appellant has provided a detailed chemical structure by way of the claimed nucleic acid molecule encoding SEQ ID NO: 2, as well as complements and specified variations thereof. This chemical structure clearly distinguishes molecules in the claimed genus from molecules not in the claimed genus. Appellant has therefore satisfied the *Eli Lilly* test for written description.

Appellant's present disclosure not only provides the nucleotide sequences required by the claims (*e.g.*, those encoding SEQ ID NO: 2, for example, SEQ ID NO: 1), but further describes that the claimed nucleic acid molecules may include the recited sequence with additional sequences, for example, vectors comprising the claimed nucleic acid molecules (*see, e.g.*, specification at page 39, line 30 through page 42, line 20). The specification also

describes, for example, nucleic acid molecules comprising single nucleotide polymorphisms (SNPs) and methods to identify sequences containing them (*see, e.g.*, specification at page 28, lines 21-24), nucleic acid molecules encoding amino acid sequences having conservative substitutions (*see, e.g.*, specification at page 15, line 19 through page 16, line 12), fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.*, specification at page 37, line 31 through page 38, line 2), plant and other homologue proteins and nucleic acid molecules (*see, e.g.*, specification at page 38, lines 3-13) and the disclosure of hybridization conditions (*see, e.g.*, specification at page 17, line 9 through page 18, line 7). Such detailed description of variations further indicates Appellant has satisfied the written description requirement.

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art, as of the filing date sought, that Appellant was in possession of the invention as now claimed. *See, e.g.*, *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q. 2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); M.P.E.P. § 2163.02. In light of the disclosure made by Appellant in the application, as discussed in details earlier, the Examiner failed to provide reasons why a person skilled in the art at the time application was filed would not have recognized that Appellant was in possession of the invention as claimed, and offered no evidence to demonstrate why one of ordinary skill in the art would reasonably doubt that the invention has not been adequately described in the present disclosure. As such, the Examiner has not met the burden to impose a written description rejection.

Appellant has provided a detailed chemical structure, *e.g.*, nucleic acid sequences encoding the amino acid sequence of SEQ ID NO: 2. Nucleic acid molecules falling within the scope of claims 3-5 are readily identifiable – *e.g.* they either contain the nucleic acid sequence which can encode an amino acid sequence that is substantially identical to a sequence of SEQ ID NO:2, or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. Thus, contrary to the Examiner's allegation, claims 3-5 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

C. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claims 3-5 has also been challenged by the Examiner because "[t]he specification does not enable any person skilled in the art to which it pertains, or with which it is mostly nearly connected, to make and/or use the invention commensurate in scope with these claims," "for the reasons of record set forth in the Official action mailed 5/19/2004." Final Action at page 5.

More particularly, the Examiner alleges that "the specification, while being enabling for isolated nucleic acid sequences encoding SEQ ID NO:2 and plant transformation therewith, does not reasonably provide enablement for nucleic acid sequences encoding a polypeptide having an amino acid sequence that is substantially identical to SEQ ID NO:2, an isolated nucleic acid molecule comprising a nucleotide sequence that hybridizes under stringent conditions to a nucleic acid encoding a polypeptide having substantial identity to SEQ ID NO:2 or an isolated nucleic acid sequence which encodes an amino acid sequence

comprising SEQ ID NO:2 containing conservative amino acid substitutions and plant transformation therewith." Final Action at pages 4-5. The Examiner specifically alleges that "[t]he claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors," Office Action mailed 5/19/2004 at page 6, and "undue experimentation would be required to practice the claimed invention given the lack of guidance and/or examples in using non-exemplified nucleic acid sequences" considering "the multitude of sequences encompassed by Applicants' claims." Final Action at page 6. Contrary to Examiner's allegation, the specification clearly enables one skilled in the art to make and use the invention without undue experimentation.

It is well-established patent jurisprudence that applications need not teach "conventional and well-known genetic engineering techniques." *See, e.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000). Furthermore, an analysis of the criteria presented by *In re Wands* supports Appellant's position that no undue experimentation would be required to make and use the claimed invention. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1998).

The first *Wands* criterion is the quantity of experimentation necessary. Despite the "multitude of sequences encompassed by" the claims, the "make-and-test" quantum of experimentation is reduced by the extensive knowledge, *e.g.*, of conservative nucleotide substitutions, identification of an active site, and conserved regulatory elements, to which a person of ordinary skill in the art has access. Furthermore, performing routine and well-known steps, such as sequence alignment protocols, transformations and gene expression

analysis, cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

The second and third *Wands* criteria relate to the amount of direction or guidance given, and the presence or absence of working examples. Again, the specification provides evidence of sequence identity, discloses the identification of promoter regions associated with the claimed nucleic acid molecule, and discusses the use of the claimed nucleic acid sequence to isolate additional sequences within a genome. *See, e.g.,* specification at page 14, line 26 through page 16, line 12, page 28, line 25 through page 31, line 28, page 47, line 25 through page 54, line 4 (Examples 1-5) and the sequence listing. Based on such disclosure, one of ordinary skill in the art would be enabled to make and use the invention commensurate in scope with the claims despite the "multitude of sequences" involved.

The fourth, fifth and sixth *Wands* criteria focuses on the nature of the invention, the state of the art and the relative skill in the art. The present invention relates to nucleic acid sequences, and the specification further describes amino acid sequences derived therefrom, antibodies, constructs and methods related thereto. *See, e.g.,* specification at page 13, line 3 through page 16, line 12 (describing polypeptide molecules and homologues), page 38, line 14 through page 39, line 2 (describing antibodies binding specifically to polypeptide molecules and homologues), and page 39, line 4 through page 47, line 17 (describing use of the claimed nucleic acid molecules in forming recombinant DNA constructs and in methods of transforming plants). Practitioners in this art are guided by considerable knowledge and resources on the conditions and approaches that can be utilized to identify, confirm and introduce into other hosts nucleic acid and amino acid sequences.

The seventh criterion considers the predictability of the art. The Examiner has presented no evidence why one of ordinary skill in the art would not, for example, be able to predict conservative substitutions or use the nucleic acid molecules of the present invention in the disclosed uses. The specification discloses sufficient guidance to render these results predictable. *See, e.g.*, Specification at page 10, line 12 through page 16, line 12, and page 47, line 25 through page 85, line 22 (Examples 1-37).

The eighth criterion focuses on the breadth of the claims. Enablement is satisfied when the disclosure "adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility". *See In re Vaeck,* 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). In the present case, one of skill in the art is specifically guided by the disclosure to look to, *e.g.*, sequence identity data in making that determination.

In addition to the above analysis of the *Wands* factors, it is well-established that specification that discloses how to use a claimed invention "must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein." *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), *quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original). The Examiner has provided neither evidence supporting the rejection nor any explanation of why the specification allegedly fails to enable claims 3-5. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (B.P.A.I. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement). Examiner has not met the required burden to impose an enablement rejection.

The above analysis illustrates that the specification clearly enables at least the methods of making and using the invention as set forth in the specification, and the enablement requirement has thus been satisfied. *See Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) ("the enablement requirement is met if the description enables any mode of making and using the invention") (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Moreover, the analysis of the *Wands* factors conclusively establishes that one of ordinary skill in the art would be able to make and use the claimed invention based on the disclosure in the specification without undue experimentation. Furthermore, the Examiner has failed to meet the burden to show why the specification allegedly fails to enable the claimed invention. Accordingly, the rejection of claims 3-5 under 35 U.S.C. § 112, first paragraph is improper and should be reversed.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Date: May 23, 2005

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APPENDIX A

Claims as Pending

1-2. (Cancelled)

3. An isolated nucleic acid molecule comprising a nucleotide sequence, or its complement, which can encode a polypeptide having an amino acid sequence that is substantially identical to a sequence of SEQ ID NO: 2.

4. An isolated nucleic acid molecule comprising a nucleotide sequence, or its complement, which can hybridize under stringent conditions to a second nucleic acid sequence which can encode a protein with substantial identity to SEQ ID NO: 2.

5. An isolated nucleic acid sequence which encodes an amino acid sequence comprising SEQ ID NO; 2 containing conservative amino acid substitutions.

6. (Allowed) An isolated nucleic acid sequence which encodes an amino sequence comprising SEQ ID NO: 2.

7-34. (Cancelled)

APPENDIX B

RELATED PROCEEDINGS APPENDIX